104TH CONGRESS 1ST SESSION

H. R. 1352

To amend the Federal Insecticide, Fungicide, and Rodenticide Act with respect to the minor use of a pesticide.

IN THE HOUSE OF REPRESENTATIVES

March 29, 1995

Mr. De la Garza (for himself, Mr. Roberts, Mr. Emerson, Mr. Condit, Mr. Stenholm, Mr. Boehner, Mrs. Thurman, Mr. Canady of Florida, Mr. Rose, Mr. Ewing, Mr. Dooley, and Mr. Pomeroy) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act with respect to the minor use of a pesticide.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Minor Use Crop Protection Act of 1995".
- 6 (b) Reference.—Whenever in this Act an amend-
- 7 ment or repeal is expressed in terms of an amendment
- 8 to, or repeal of, a section or other provision, the reference
- 9 shall be considered to be made to a section or other provi-

1	sion of the Federal Insecticide, Fungicide, and
2	Rodenticide Act.
3	SEC. 2. MINOR CROP PROTECTION.
4	(a) Definition.—Section 2 (7 U.S.C. 136) is
5	amended by adding at the end the following:
6	"(hh) MINOR USE.—The term 'minor use' means the
7	use of a pesticide on an animal, on a commercial agricul-
8	tural crop or site, or for the protection of public health
9	where—
10	"(1) the total United States acreage for the
11	crop is less than 300,000 acres; or
12	"(2) the Administrator, in consultation with the
13	Secretary of Agriculture, determines that, based on
14	information provided by an applicant for registration
15	or a registrant, the use does not provide sufficient
16	economic incentive to support the initial registration
17	or continuing registration of a pesticide for such use;
18	and—
19	"(A) there are insufficient efficacious alter-
20	native registered pesticides available for the
21	use; or
22	"(B) the alternatives to the pesticide pose
23	greater risks to the environment or human
24	health; or

"(C) the pesticide plays or will play, a sig-1 2 nificant part in managing pest resistance; or "(D) the pesticide plays or will play a sig-3 4 nificant part in an integrated pest management program. The status as a minor use under this subsection 6 7 shall continue as long as the Administrator has not determined that, based on existing data, such use 8 9 may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such 10 11 status.". 12 (b) Exclusive Use of Minor Use Pesticides.— Section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)) is amended by redesignating clauses (ii) and (iii) as clauses (iii) and 14 15 (iv), respectively, and by inserting after clause (i) the following: 16 17 "(ii) The period of exclusive data use 18 for data submitted to support the applica-19 tion for the original registration of a pesticide under clause (i) shall be extended 20 one additional year for each 3 minor uses 21 22 registered after the date of enactment of this clause and, before the expiration of 23 the period of exclusive use under this 24 clause, up to a total of 3 additional years 25

1	for all minor uses registered by the Admin-
2	istrator if the Administrator in consulta-
3	tion with the Secretary of Agriculture de-
4	termines that, based on information pro-
5	vided by an applicant for registration or a
6	registrant, that:
7	"(I) there are insufficient effica-
8	cious alternative registered pesticides
9	available for the use; or
10	"(II) the alternatives to the pes-
11	ticide pose greater risks to the envi-
12	ronment or human health; or
13	"(III) the pesticide plays or will
14	play a significant part in managing
15	pest resistance; or
16	"(IV) the pesticide plays or will
17	play a significant part in an inte-
18	grated pest management program.
19	The registration of a pesticide for a minor
20	use on a crop grouping established by the
21	Administrator shall be considered for pur-
22	poses of this clause one minor use for each
23	representative crop for which data are pro-
24	vided in the crop grouping. Any additional
25	exclusive use period under this clause shall

be modified as appropriate or terminated if
the registrant voluntarily cancels the product or deletes from the registration the
minor uses which formed the basis for the
extension of the additional exclusive use
period or if the Administrator determines
that the registrant is not actually marketing the product for such minor uses.".

(c) TIME EXTENSIONS FOR DEVELOPMENT OF

- 9 (c) Time Extensions for Development of 10 Minor Use Data.—
 - (1) DATA CALL-IN.—Subparagraph (B) of section 3(c)(2) (7 U.S.C. 136a(c)(2)(B)) is amended by adding at the end the following:

"(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data are required solely to support that minor use until the final deadline for submission of data under section 4 for the other uses of the pesticide established as of the date of enactment of the Minor Use Crop Protection Amendments of 1995, if—

1	"(I) the data to support other
2	uses of the pesticide on a food are
3	being provided;
4	"(II) the registrant, in submit-
5	ting a request for such an extension,
6	provides a schedule, including interim
7	dates to measure progress, to assure
8	that the data production will be com-
9	pleted before the expiration of the ex-
10	tension period;
11	"(III) the Administrator has de-
12	termined that such extension will not
13	significantly delay the Administrator's
14	schedule for issuing a reregistration
15	eligibility determination required
16	under section 4; and
17	"(IV) the Administrator has de-
18	termined in writing that based on ex-
19	isting data, such extension would not
20	significantly increase the risk of any
21	unreasonable adverse effect on the en-
22	vironment.
23	If the Administrator grants an extension
24	under this clause, the Administrator shall
25	monitor the development of the data and

1 shall ensure that the registrant is meeting 2 the schedule for the production of the data. If the Administrator determines that 3 the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed 6 7 in accordance with clause (iv) regarding the continued registration of the affected 8 9 products with the minor use and shall inform the public of such action. Notwith-10 11 standing the provisions of this clause, the Administrator may take action to modify 12 13 or revoke the extension under this clause if the Administrator determines that the ex-14 15 tension for the minor use may cause an unreasonable adverse effect on the environ-16 17 ment. In such circumstance, the Adminis-18 trator shall provide, in writing to the reg-19 istrant, a notice revoking the extension of 20 time for submission of data. Such data 21 shall instead be due in accordance with the 22 date than established by the Administrator 23 for the submission of the data.". 24 (2)REREGISTRATION.—Sections 4(d)(4)(B),

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4(e)(2)(B).

and

4(f)(2)(B)

1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each amended by adding at the end the following: "Upon the request of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Minor Use Crop Protection Amendments of 1995 if—

- "(i) the data to support other uses of the pesticide on a food are being provided;
- "(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;
- "(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

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"(iv) the Administrator has determined in writing that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment.

If the Administrator grants an extension under subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse affect on the environment. In such circumstance, the Administrator shall

1	provide, in writing to the registrant, a notice re-
2	voking the extension of time for submission of
3	data. Such data shall instead be due in accord-
4	ance with the date then established by the Ad-
5	ministrator for submission of the data.".
6	(d) Minor Use Waiver.—Section 3(c)(2) (7 U.S.C.
7	136a(c)(2)) is amended—
8	(1) by inserting "In GENERAL.—" after "(A)",
9	by inserting "Additional data.—" after "(B)",
10	and by inserting "SIMPLIFIED PROCEDURES.—"
11	after "(C)", and
12	(2) by adding at the end the following:
13	"(E) Minor use waiver.—In handling
14	the registration of a pesticide for a minor use,
15	the Administrator may waive otherwise applica-
16	ble data requirements if the Administrator de-
17	termines that the absence of such data will not
18	prevent the Administrator from determining—
19	"(i) the incremental risk presented by
20	the minor use of the pesticide, and
21	"(ii) that such risk, if any, would not
22	be an unreasonable adverse effect on the
23	environment.".
24	(e) Expediting Minor Use Registrations.—Sec-
25	tion 3(c)(3) (7 U.S.C. 136a(c)(3)) is amended—

1	(1) by inserting after "(A)" the following: "IN
2	GENERAL.—";
3	(2) by inserting after "(B)" the following:
4	"IDENTICAL OR SUBSTANTIALLY SIMILAR.—"; and
5	(3) by adding at the end the following:
6	"(C) Minor use registration.—
7	"(i) The Administrator shall, as expe-
8	ditiously as possible, review and act on any
9	complete application—
10	"(I) that proposes the initial reg-
11	istration of a new pesticide active in-
12	gredient if the active ingredient is
13	proposed to be registered solely for
14	minor uses, or proposes a registration
15	amendment solely for minor uses to
16	an existing registration, or
17	"(II) for a registration or a reg-
18	istration amendment that proposes
19	significant minor uses.
20	"(ii) For the purposes of clause (i)—
21	"(I) the term 'as expeditiously as
22	possible' means that the Adminis-
23	trator shall to the greatest extent
24	practicable complete a review and
25	evaluation of all data, submitted with

complete application, within 1 months after the submission of the 2 complete application, and the failure 3 of the Administrator to complete such a review and evaluation under clause 5 (i) shall not be subject to judicial re-6 7 view, and "(II) the term 'significant minor 8 9 uses' means 3 or more minor uses 10 proposed for every non-minor use, a 11 minor use that would, in the judgment of the Administrator, serve as a re-12 placement for any use which has been 13 14 canceled in the 5 years preceding the 15 receipt of the application, or a minor use that in the opinion of the Admin-16 17 istrator would avoid the reissuance of 18 an emergency exemption under section 19 18 for that minor use. "(D) ADEQUATE TIME FOR SUBMISSION OF 20 MINOR USE DATA.—If a registrant makes a re-21 22 quest for a minor use waiver, regarding data re-23 quired by the Administrator, pursuant to para-24 graph (2)(E), and if the Administrator denies

in whole or in part such data waiver request,

the registrant shall have a full time period for providing such data. For purposes of this sub-paragraph, the term 'full time period' means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.".

8 (f) Temporary Extension of Registration for 9 Unsupported Minor Uses.—

(1) Reregistration.—

(A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C. 136a–1(d)(6) and (f)(3)) are each amended by adding at the end the following: "If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to

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such unsupported minor use until the final deadline established as of the date of enactment of the Minor Use Crop Protection Amendments of 1995, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may

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proceed in accordance with clause (iv) of section 3(c)(2)(B) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding the provision of this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation the Administrator shall provide, in writing, to the registrant, a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B) Section 4(e)(3)(A) (7 U.S.C. 136a–(e)(3)(A)) is amended by adding at the end the following: "If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does

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not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Minor Use Crop Protection Amendments of 1995, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this subpara-

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graph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding the provisions of this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant, a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

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(2) DATA.—Section 3(c)(2)(B) (7 U.S.C. 136a(c)(2)(B)), as amended by subsection (c), is further amended by adding at the end the following:

"(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Minor Use Crop Protection Amendments of 1995, for the submission of data under section 4 for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to

cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance

with section 6(f)(2). Notwithstanding the 1 2 provisions of this clause, the Administrator may deny, modify, or revoke the temporary 3 extension under this subparagraph if the Administrator determines that the continu-6 ation of the minor use may cause an unreasonable adverse effect on the environ-7 8 ment. In the event of modification or rev-9 ocation, the Administrator shall provide, in 10 writing, to the registrant, a notice revoking the temporary extension and establish a 12 new effective date by which the minor use shall be deleted from the registration. 13

14 (g) Utilization of Data for Voluntarily Can-15 CELED CHEMICALS.—Section 6(f) (7 U.S.C. 136d) is amended by adding at the end the following: 16

> "(4) Utilization of data for voluntarily CANCELED CHEMICALS.—When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had

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- 1 not yet taken place, except that the Administrator
- 2 shall not take such action if the Administrator deter-
- 3 mines that such minor use may cause an unreason-
- 4 able adverse effect on the environment. In order to
- 5 rely on this paragraph, the applicant must certify
- 6 that it agrees to satisfy any outstanding data re-
- 7 quirements necessary to support the reregistration of
- 8 the pesticide in accordance with the data submission
- 9 schedule established by the Administrator.".
- 10 (h) Environmental Protection Agency Minor
- 11 USE PROGRAM.—The Federal Insecticide, Fungicide, and
- 12 Rodenticide Act (7 U.S.C. 136 et seq.) is amended by re-
- 13 designating sections 30 and 31 as sections 32 and 33, re-
- 14 spectively and adding after section 29 the following:
- 15 "SEC. 30. ENVIRONMENTAL PROTECTION AGENCY MINOR
- 16 **USE PROGRAM.**
- 17 "The Administrator shall assure coordination of
- 18 minor use issues through the establishment of a minor use
- 19 program within the Office of Pesticide Programs. Such of-
- 20 fice shall be responsible for coordinating the development
- 21 of minor use programs and policies and consulting with
- 22 growers regarding minor use issues and registrations and
- 23 amendments which are submitted to the Environmental
- 24 Protection Agency.".

1	(i) Department of Agriculture Minor Use
2	PROGRAM.—The Federal Insecticide, Fungicide, and
3	Rodenticide Act (7 U.S.C. 136 et seq.), as amended by
4	subsection (h), is amended by adding after section 30 the
5	following:
6	"SEC. 31. DEPARTMENT OF AGRICULTURE MINOR USE PRO-
7	GRAM.
8	"(a) In General.—The Secretary of Agriculture
9	(hereinafter in this section referred to as the 'Secretary')
10	shall ensure the coordination of the responsibilities of the
11	Department of Agriculture related to minor uses of pes-
12	ticides, including—
13	"(1) carrying out the Inter-Regional Project
14	Number 4 (IR-4) as described in section 2(e) of the
15	Act entitled 'An Act to facilitate the work of the De-
16	partment of Agriculture, and for other purposes' (7
17	U.S.C. 4501(e)) and the national pesticide resistance
18	monitoring program established under section 1651
19	of the Food, Agriculture, Conservation, and Trade
20	Act of 1990 (7 U.S.C. 5882);
21	"(2) supporting integrated pest management
22	research;
23	"(3) consulting with growers to develop data for
24	minor uses; and

1 "(4) providing assistance for minor use reg-2 istrations, tolerances, and reregistrations with the 3 Environmental Protection Agency.

"(b) MATCHING FUND PROGRAM.—

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"(1) ESTABLISHMENT.—The Secretary of Agriculture, in consultation with the Administrator, shall establish and administer a minor use matching fund program. The matching fund program shall be utilized to ensure the continued availability of minor use crop protection chemical, including the development of data to support minor use pesticide registrations and reregistrations. Access to the matching fund program shall be available to any entity which desires to develop data to support minor use registrations. Priority for access to the fund shall be given those entities that do not directly receive funds from the sale of products registered on minor uses. Any entity that seeks such funding under this paragraph shall be required to match such funds with an equal amount of its own funds. Any data developed through the matching fund program shall be jointly owned by the Department of Agriculture and by the entity that receives such funding. Any data developed under this subsection shall be subject to the provisions of section 3(c)(1)(F). All compensation received by the Department of Agriculture in return for the use of such data under the matching fund program shall be returned to a revolving fund which will support the matching fund program.

"(2) AUTHORIZATION.—There is authorized to be appropriated for the revolving fund for the matching fund program an annual sum not to exceed \$10,000,000.".

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